

REMARKS

The present claims relate to a reagent kit.

Status of the claims

In the Office Action, claims 2, 4, 5, and 7 were rejected under 35 U.S.C. § 112 for allegedly being indefinite. Claims 1-3 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by JP 5180835 (“JP ‘835”). In addition, claims 1, 3, and 4 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over JP ‘835 in view of Hoogendoorn et al. (U.S. Patent No. 6,432,658) (hereinafter “Hoogendoorn”). Claims 5-9 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over JP ‘835 in view of Griffin et al. (U.S. Patent No. 5,834,223) and Zuk et al. (U.S. Patent No. 4,281,061) (hereinafter “Griffin” and “Zuk,” respectively). Further, claims 1-9 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Griffin as evidenced by the article by Galli et al. in view of Lenz et al. (U.S. Patent No. 4,914,040) (hereinafter “Galli” and “Lenz,” respectively). Claims 1-2 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-8 of copending Application No. 10/995,382. Moreover, claims 1 and 3-5 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-11 of copending Application No. 10/995,382 in view of Hoogendoorn. Finally, claims 6-9 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as

allegedly being unpatentable over claims 1-11 of copending Application No. 10.995,382 in view of Griffin and Zuk.

Amendment summary

Upon entry of this Amendment, claims 6, 8-9, and 15-22 will be pending.

Claims 1-5, 7, and 10-14 are canceled.

The specification is amended to remove a typographical error, where celite was spelled “sellaite.”

The specification is also amended in various places to capitalize listed trademarks.

Claims 6 and 9 are amended to recite that the anti-phospholipid antibody capturing component is selected from the group consisting of antibodies, plasma, serum and immunoglobulin, and is derived from vertebrate animals other than human. Support for these amendments may be found, e.g., in the paragraph bridging pages 9-10 of the specification.

Claim 9 is further amended to recite an “activator,” which was, through a typographical error, previously erroneously referred to as a “contacting factor.” Support for this amendment is found, e.g., at page 14, line 5 of the specification.

Claim 9 is also amended to recite that the third reagent does not contain the anti-phospholipid antibody capturing component. Support for this amendment may be found, e.g., in the first paragraph of page 13 of the specification.

Claims 15-22 are supported by the specification, e.g., in the manner depicted in the following table:

<u>Claim</u>	<u>Support</u>
15	Original claim 3, the second paragraph on page 9, and the paragraph bridging pages 13-14 of the specification
16	Original claim 3, the second paragraph on page 9, and the paragraph bridging pages 13-14 of the specification
17	Original claim 3, the second paragraph on page 9, and the paragraph bridging pages 13-14 of the specification
18	Original claim 2 and the paragraph bridging pages 10-11 of the specification
19	Original claim 3 and the paragraph bridging pages 13-14 of the specification
20	Original claim 4 and the paragraph bridging pages 8-9 of the specification
21	Pages 9-10 and 13-15 and Examples 1-4 of the specification
22	Pages 9-10 and 13-15 and Examples 1-4 of the specification

No new matter is added by this Amendment, and Applicant respectfully submits that entry of this Amendment is proper.

Response to trademark comments

On page 2 of the Office Action, the Examiner notes that some trademarks have not been capitalized in the present specification. Applicant has amended the specification to capitalize the trademarks listed in the office action.

Response to rejections of (1) claims 2, 4, 5, and 7 under 35 U.S.C. § 112; (2) claims 1-3 under 35 U.S.C. § 102 based on JP '835; (3) claims 1, 3, and 4 under 35 U.S.C. § 103 based on JP '835 in view of Hoogendoorn; (4) claims 1-2 on the ground of nonstatutory obviousness-type double patenting based on claims 1-8 of copending Application No. 10/995,382; and (5) claims 1 and 3-5 on the ground of nonstatutory obviousness-type double patenting based on claims 1-11 of copending Application No. 10/995,382 in view of Hoogendoorn

Applicant notes that claims 1-5 and 7 are now canceled, thereby rendering each of the foregoing rejections moot. Applicant respectfully requests the withdrawal of each of these rejections.

Response to rejection of claims 5-9 under 35 U.S.C. § 103 based on JP '835 in view of Griffin and Zuk

As an initial matter, Applicant notes that claims 5 and 7 are now canceled, thereby rendering the rejections of those claims moot. Applicant accordingly respectfully requests the withdrawal of this rejection as it pertains to claims 5 and 7.

The present claims recite that a first coagulation time reagent contains an anti-phospholipid antibody capturing component derived from vertebrate animals other than human that is selected from the group consisting of antibodies, plasma, serum and immunoglobulin. In addition, a second coagulation time reagent does not contain the anti-phospholipid antibody capturing component.

Accordingly, a sample can be judged as LA positive, when the first coagulation time of the sample measured with use of the inventive reagent kit is shorter than the second coagulation time of the sample. Such a process is described on, for example, the first full paragraphs on both pages 13 and 14 of the present specification.

Applicant respectfully submits that the combined teachings of JP '835, Griffin, and Zuk do not render obvious the present claims. Specifically, Applicant notes that none of these references disclose a first coagulation time reagent that contains a first composition for coagulation and an anti-phospholipid antibody capturing component selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, with the anti-phospholipid antibody capturing component derived from vertebrate animals other than humans.

JP '835 (with respect to which a machine-assisted translation is included with the Information Disclosure Statement filed concurrently with this Amendment) discloses a LA

detecting method comprising adding phospholipids and calcium ion and protein C to the plasma that is to be measured, in order to trigger coagulation. The coagulation time of the plasma is measured, and it is judged whether the plasma is LA based upon whether the coagulation time of the plasma is shorter than the coagulation time of normal plasma. According to the method of JP '835, the blood plasma is supplied from the sample to be measured, and is not contained in the detective reagent.

Accordingly, Applicant respectfully submits that JP '835 does not disclose or teach a reagent that contains plasma as a component. Additionally, Applicant respectfully submits that JP '835 does not disclose or teach a reagent kit that comprises a first reagent containing an anti-phospholipid antibody capturing component and a second reagent that does not contain an anti-phospholipid antibody capturing component.

Applicant respectfully submits that this JP '835 deficiency is not cured by either Griffin or Zuk. Applicant respectfully submits that Griffin does not disclose or teach a coagulation time reagent containing a first composition for coagulation and an anti-phospholipid antibody capturing component that is selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, where the anti-phospholipid antibody capturing component is derived from vertebrate animals other than humans. Applicant also respectfully submits that Zuk also does not disclose or teach the first coagulation time reagent of the present claims.

Therefore, Applicant respectfully submits that the combined teachings of JP '835, Griffin, and Zuk do not render obvious the present claims. Applicant therefore respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Response to rejection of claims 1-9 under 35 U.S.C. § 103 based on Griffin as evidenced by Galli and in view of Lenz

As an initial matter, Applicant notes that claims 1-5 and 7 are now canceled, thereby rendering the rejections of those claims moot. Applicant accordingly respectfully requests the withdrawal of this rejection as it pertains to claims 1-5 and 7.

Applicant respectfully submits that, as discussed above, Griffin does not disclose or teach a coagulation time reagent containing a first composition for coagulation and an anti-phospholipid antibody capturing component that is selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, where the anti-phospholipid antibody capturing component is derived from vertebrate animals other than humans.

Applicant respectfully submits that neither Galli nor Lenz discloses the first coagulation time reagent of the present claims, either.

Therefore, Applicant respectfully submits that this combination of references does not render obvious the present claims. Applicant accordingly respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Response to provisional obviousness-type double patenting rejection of claims 6-9 based on claims 1-11 of copending Application No. 10/995,382 in view of Griffin and Zuk

Applicant respectfully submits that the present claims are not obvious in view of claims 1-11 of the '382 Application, as those claims were amended on November 27, 2006.

As an initial matter, the claims in the '382 Application do not recite a second coagulation time reagent containing a second composition for coagulation in the absence of an anti-phospholipid antibody capturing component, as recited by the present claims.

Moreover, Applicant respectfully submits that the '382 Application relates to a clotting time-measuring reagent that allows an accurate measurement with a sample containing anti-phospholipid antibodies, rather than a reagent for detecting LA.

Furthermore, Applicant again notes that both Griffin (relating to a reagent kit for detecting a thrombotic disorder associated with APC) and Zuk (relates to a reagent kit used in immunoassay) do not relate to the '382 Application, which provides a reagent capable of measuring an accurate clotting time - even if a sample contains anti-phospholipid antibodies such as LA. Applicant therefore respectfully submits that there is no motivation to combine these references to arrive at the presently claimed subject matter.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 10/811,385

Attorney Docket No.: Q80589

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this obviousness-type double patenting rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby earnestly solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local Washington, DC, telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

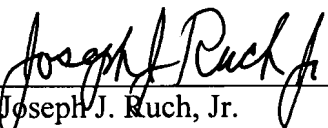
Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER


Joseph J. Ruch, Jr.
Registration No. 26,577

Date: April 6, 2007